

REMARKS

Claims 1, 4, 5-6, 9-11, 13, 15, 17, and 19 remain in this application, and are not amended by this response.

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph failing to comply with the written description requirement. This rejection is respectfully traversed.

During a telephone interview with the examiner on November 30, 2009, I explained where the present patent application supports the claimed limitation of "an amount of at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day." Specifically, my application discloses 6000 mg per day (in Table I, last row, p. 7) divided by 45 kg (from p. 6, discussing Table I) which equals 133.33 mg/kg. On page 7, I round this up to 135 mg/kg. During the interview, after the basis for the 133 mg/kg figure had been explained to her, the examiner agreed that the application provides adequate written support for the claim as written. Therefore, there should be no need to amend the claim to recite the 135 mg/kg figure, and this rejection should be withdrawn.

Claims 1, 4, 6, 9-11, 13, 15, 17 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Herschler (US 4863748) in view of Webster's Ninth New Collegiate Dictionary (1991) ("Webster's") and Salim (WO 94/05279). These rejections are respectfully traversed.

These rejections rest on erroneous findings regarding Herschler's disclosure, among other things. The arguments presented in my last response, showing that Herschler fails to disclose administering an effective amount of MSM to cause noticeable skin lightening, have apparently been accepted. The present Office Action raises no counterarguments on this point. However, with respect to claim 1, the Office Action instead erroneously finds that Herschler combined with Webster's definition of "complexion" teaches the element of **"delivering an effective amount of methyl sulfonyl methane to a person for developing a lighter skin tone by ingestion of**

**the effective amount, at least until the person develops a skin tone noticeably lighter than before commencement of the delivery step.”** The Office Action argues that because Herschler teaches that MSM can be used to “beautify the complexion” and Webster’s teaches that “complexion” can refer to skin tone, it follows that Herschler teaches this claim element. Office Action, p. 3. This is not a reasonable argument or conclusion, when one reviews the entirety of Herschler and its use of the term “complexion.” Although we were unable to resolve this disagreement during the November 30<sup>th</sup> telephone interview, the examiner suggested that I might submit further evidence and arguments on this point. Therefore, I obtained expert declarations regarding the extent of Herschler’s disclosure and other issues. These declarations are submitted with this response and discussed below.

Two declarations accompany this response: The Declaration of Dr. Nikolay N. Barashkov (“Barashkov”) and The Declaration of Sherilee J. Backman (“Backman”). Several key factual points made by Dr. Barashkov and Ms. Backman in their Declarations are summarized below. Please refer directly to the Declarations for further details supporting Dr. Barashkov’s and Ms. Backman’s findings.

1. The phrase “beautify the complexion,” as used by Herschler refers to the cosmetic effect of providing the skin a softer, smoother texture and appearance. Barashkov ¶ 4; Backman ¶ 5.
2. The entire disclosure of Herschler shows absolutely no recognition or conception that MSM has any effect on skin tone. Barashkov ¶ 5; Backman ¶ 6.
3. Both organic and cosmetic chemists would have understood the phrase “beautify the complexion” as used by Herschler to refer only to the softening and smoothing effect of MSM that Herschler described, and not to any skin lightening effect. Barashkov ¶ 6-8; Backman ¶ 7.

The testimony of Dr. Barashkov and Ms. Backman, in light of the disclosure of Herschler and Webster's definition of "complexion," clearly shows that Herchsler fails to disclose or suggest **"delivering an effective amount of methyl sulfonyl methane to a person for developing a lighter skin tone by ingestion of the effective amount, at least until the person develops a skin tone noticeably lighter than before commencement of the delivery step."** Reconsideration of the Office Action's finding to the contrary is respectfully requested.

As acknowledged in the Office Action, Herschler also fails to disclose **"wherein the effective amount comprises orally administered doses in an amount of at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months,"** as also defined by claim 1. The Office Action cites Salim as disclosing this element. Reconsideration of this finding is also respectfully requested, for reasons set forth below. It should be acknowledged that Salim fails to disclose or suggest that MSM or anything else can be used to lighten skin tone, and is not generally concerned with skin tone.

Salim discloses an oral dose of MSM in units of 100 to 500 mg "at intervals of from 2 to 8 hours, most preferably every 6 hours" for therapeutic purposes such as healing injured skin, in combination with a sulfur-containing amino acid. Salim, p. 7 first paragraph; Backman ¶ 9. A cosmetic chemist of ordinary skill would understand Salim as disclosing a maximum dose of MSM in the range of 1500-2000 mg per day (500 mg three or four times daily, or smaller doses more frequently), in combination with one or more sulfur-containing amino acids in the same dosage range. Backman ¶ 9. For a 45 kg adult female, Salim therefore discloses a maximum dose of MSM in the range of 33 to 44 mg/kg/day. Backman ¶ 9. Therefore, a reasonable reading of Salim leads to the conclusion that Salim taught maximum oral doses of MSM significantly less than claimed.

Moreover, there would have been no motivation for someone reading Herschler and Salim to discover the dose regimen defined by claim 1, because lower doses were

already known to be effective for all known cosmetic and therapeutic applications, as demonstrated by the Herschler and Salim references. Backman ¶ 10. There was no suggestion that higher doses of MSM would produce any beneficial effect, so there would have been no reason to experiment with higher doses. *Id.* For example, Salim teaches that increasing the concentration of MSM does not provide any additional benefit in reducing tissue injury, as reported in its tables on pages 11 and 13. Therefore, Salim provides no incentive to experiment with higher doses, and if anything, might have discouraged such experimentation by reporting that increased concentrations of MSM provide no additional benefit. Backman ¶ 11.

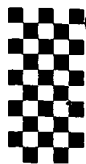
In addition, MSM's skin lightening effects would not have been considered expected or predictable at the time these effects were first reported by me in the present application. Backman ¶ 8. Skin lightening is an unexpected result of administering MSM. Barashkov ¶ 9.

In summary of the foregoing, the evidence shows that the combination of Herschler, Webster's and Salim fails to disclose each and every element of claim 1. The references and enclosed declarations also show that those of skill in the art would have had no motivation to administer the claimed oral doses. In addition, the declaration show that the skin lightening effect provided by the claimed dose regimen would have been unexpected. Claim 1 therefore recites a combination of elements that was not known, and would not have been obvious at the time the invention was made.

In view of the deficiencies of Herschler, Webster's and Salim outlined above, these references pose no bar to patentability of claim 1, which is therefore allowable. The remaining claims are also allowable, at least as depending from an allowable base claim.

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In view of the foregoing, the Applicant respectfully submits that claims 1, 4, 5-6, 9-11, 13, 15, 17, and 19 are in condition for allowance. Reconsideration and withdrawal



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of the rejections is respectfully requested, and a timely Notice of Allowability is solicited.

The arguments presented herein are sufficient to fully traverse the rejections set forth in the Office Action. Therefore, I have not presented all possible arguments, and may not have refuted the characterizations of either the claims or the prior art as may be found in the record. However, the lack of such arguments or refutations is not intended to waive such arguments or indicate concurrence with such characterizations.

Respectfully submitted,

Date: January 29, 2010

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Applicant